

What is claimed is:

1      1. A medical device, comprising:  
2                a substrate that is expandable from a compressed  
3                state to an expanded state;  
4                a coating on said substrate, said coating having a  
5                drug agent incorporated therein; and  
6                a sheath over said coating, said sheath being  
7                expandable from a compressed state to an expanded state  
8                and having at least one perforation therein;  
9                2) wherein when said substrate is in a compressed  
10          state, said sheath is in a compressed state and said at  
11          least one perforation is substantially closed such that  
12          said drug agent does not pass through said at least one  
13          perforation; and  
14          wherein when said substrate is in an expanded state,  
15          said sheath is in an expanded state and said at least one  
16          perforation is substantially open such that said drug  
17          agent passes through said at least one perforation.

1      2. The device of claim 1, wherein said coating comprises a  
2                polymer selected from the group consisting of  
3                polycarboxylic acids, cellulosic polymers, gelatin,  
4                polyvinylpyrrolidone, maleic anhydride polymers,  
5                polyamides, polyvinyl alcohols, polyethylene oxides,  
6                glycosaminoglycans, polysaccharides, polyesters,  
7                polyacrylamides, polyethers, polyurethane dispersions,

8           acrylic latex dispersions, and mixtures and copolymers  
9           thereof.

1           3. The device of claim 1, wherein said drug agent is  
2           selected from the group consisting of pharmaceutically  
3           active compounds, proteins, oligonucleotides, DNA  
4           compacting agents, recombinant nucleic acids, gene/vector  
5           systems, and nucleic acids.

1           4. The device of claim 1, wherein said sheath comprises a  
2           material selected from the group consisting of ethylene  
3           vinyl acetate, latexes, urethanes, polysiloxanes,  
4           styrene-ethylene/butylene-styrene block copolymers,  
5           aliphatic polyesters, and mixtures and copolymers  
thereof; and nitinol and stainless steel.

1           5. The device of claim 1, wherein said at least one  
perforation is in the shape of a longitudinal slit.

1           6. The device of claim 5, wherein said sheath comprises a  
2           plurality of perforations arranged in a staggered  
3           pattern.

1           7. The device of claim 1, wherein said substrate comprises  
2           at least part of a balloon portion of a balloon catheter.

1       8. The device of claim 7, wherein said sheath is tubular and  
2       surrounds said balloon portion of said balloon catheter,  
3       said tubular sheath having proximal and distal ends.

1       9. The device of claim 8, wherein said proximal and distal  
2       ends of said sheath are attached to said balloon catheter  
3       such that said balloon portion is completely covered by  
4       said sheath.

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1       10. The device of claim 9, wherein said proximal and distal  
2       ends of said sheath are attached to said balloon catheter  
3       by an adhesive.

1       11. The device of claim 9, further comprising a filament  
2       around said proximal and distal ends of said sheath.

1       12. A method for the localized delivery of a drug agent to a  
2       target location within a mammalian body, comprising the  
3       steps of:  
4                 providing a medical device comprising:  
5                         a substrate that is expandable from a  
6                         compressed state to an expanded state;  
7                         a coating on said substrate; and  
8                         a sheath over said coating, said sheath  
9                         being expandable from a compressed state to an  
10                         expanded state and having at least one  
11                         perforation therein;

12                         wherein when said substrate is in a  
13                         compressed state, said sheath is in a  
14                         compressed state and said at least one  
15                         perforation is substantially closed; and

16                         wherein when said substrate is in an  
17                         expanded state, said sheath is in an expanded  
18                         state and said at least one perforation in  
19                         said expandable sheath is substantially open;

20                         incorporating said drug agent into said coating;

21                         delivering said medical device to said target  
22                         location while said sheath is in a compressed state and  
23                         said at least one perforation is substantially closed;  
24                         and

25                         expanding said substrate to thereby expand said  
26                         sheath to an expanded state such that said at least one  
27                         perforation is substantially open, whereby the drug agent  
28                         passes through said at least one perforation.

1                         13. The method of claim 12, wherein said step of  
2                         incorporating the drug agent into said coating comprises  
3                         the steps of:

4                         expanding said substrate to thereby expand said  
5                         sheath such that said at least one perforation is  
6                         substantially open;

7                         exposing said drug agent to said coating through  
8                         said at least one perforation while said at least one  
9                         perforation is substantially open; and

compressing said substrate to thereby compress said sheath such that said at least one perforation is substantially closed.

14. The method of claim 13, wherein said drug agent is exposed to said coating by immersing at least part of said medical device into a solution comprising said drug agent.

15. The method of claim 12, wherein said coating comprises a polymer selected from the group consisting of polycarboxylic acids, cellulosic polymers, gelatin, polyvinylpyrrolidone, maleic anhydride polymers, polyamides, polyvinyl alcohols, polyethylene oxides, glycosaminoglycans, polysaccharides, polyesters, polyacrylamides, polyethers, polyurethane dispersions, acrylic latex dispersions, and mixtures and copolymers thereof.

16. The method of claim 12, wherein said drug agent is selected from the group consisting of pharmaceutically active compounds, proteins, oligonucleotides, genes, DNA compacting agents, gene/vector systems, and nucleic acids.

17. The method of claim 12, wherein said sheath comprises a material selected from the group consisting of ethylene vinyl acetate, latexes, urethanes, polysiloxanes.

4                   styrene-ethylene/butylene-styrene block copolymers,  
5                   aliphatic polyesters, and mixtures and copolymers  
6                   thereof; and nitinol and stainless steel.

1       18. The method of claim 12, wherein said at least one  
2                   perforation is in the shape of a longitudinal slit.

1       19. The method of claim 18, wherein said at least one  
2                   perforation comprises a plurality of perforations  
3                   arranged in a staggered pattern.

1       20. The method of claim 12, wherein said substrate comprises  
2                   at least part of a balloon portion of a balloon catheter.

1       21. The method of claim 20, wherein said sheath is tubular  
2                   and surrounds said balloon portion of said balloon  
3                   catheter, said tubular sheath having proximal and distal  
4                   ends.

1       22. The method of claim 21, wherein said proximal and distal  
2                   ends of said sheath are attached to said balloon catheter  
3                   such that said balloon portion is completely covered by  
4                   said sheath.

1       23. The method of claim 12, wherein said medical device  
2                   comprises an electroporation catheter.

24. The method of claim 12, wherein said medical device comprises an iontophoresis catheter.

25. A medical device, comprising:

a catheter comprising a balloon portion that is expandable from a compressed state to an expanded state;

a polymer coating on said balloon portion, said coating having a drug agent incorporated therein; and

a tubular sheath over said coating, said sheath being expandable from a compressed state to an expanded state and having a plurality of perforations therein, said perforations being arranged in a staggered pattern; wherein

the proximal and distal ends of said sheath are attached to said catheter such that said balloon portion is completely covered by said sheath:

when said balloon portion is in a compressed state, said sheath is in a compressed state and said perforations are substantially closed such that said drug agent does not pass through said perforations; and

when said balloon portion is in an expanded state, said sheath is in an expanded state and said perforations are substantially open such that said drug agent passes through said perforations.